AMENDMENTS TO THE CLAIMS

This listing of claims replaces all prior versions, and listings, of claims in the application.

1.-23. (Canceled)

24. (Currently Amended) A method of producing a stable, sterile pharmaceutical formulation comprising lyophilized azithromycin, which method comprises:

(a) preparing a liquid composition comprising an ethanolate of azithromycin ~~Azithromycin~~, an acid selected from the group consisting of citric acid, hydrochloric acid, lactic acid, glycolic acid, acetic acid, phosphoric acid, and tartaric acid, and an aqueous solvent,

(b) chilling the composition to a temperature from about -10° C to about 15° C, wherein the temperature is maintained for at least about 20 minutes to about 2 hours,

(c) freezing the composition to a temperature of from about -30° C to about -50° C, to produce a frozen mixture, wherein the temperature is maintained for at least about 1 hour,

(d) subjecting the frozen mixture to a primary drying stage, which comprises applying a vacuum to reduce the pressure by an amount effective to remove aqueous solvent from the frozen mixture, and, while applying the vacuum, changing the temperature of the frozen mixture to a primary drying temperature, wherein the primary drying temperature is from about 0° C to about 20° C, and wherein the primary drying temperature is maintained for at least about 20 hours to about 40 hours, to produce a first intermediate, and

(e) subjecting the first intermediate to a secondary drying stage, which comprises applying a vacuum to reduce the pressure by an amount effective to remove aqueous solvent from the first intermediate, and, while applying the vacuum, (i) changing the temperature of the first intermediate to a first secondary drying temperature, wherein the first secondary drying temperature is from about 20° C to about 40° C, and wherein the first secondary drying temperature is maintained for at least about 10 hours to about 20 hours, and (ii) changing the temperature of the first intermediate to a second secondary drying temperature, wherein the second secondary drying temperature is from about 30° C to about 50° C, and wherein the second secondary drying temperature is maintained for at least about

10 hours to about 20 hours, to produce the pharmaceutical formulation, wherein ethanol is present in an amount from about 0.005% to about 0.5% by weight of the pharmaceutical formulation.

25. (Original) The method of claim 24, wherein the composition is chilled to a temperature from about 0° C to about 10° C.

26. (Canceled)

27. (Previously Presented) The method of claim 24, wherein the composition is frozen to a temperature of about -40° C.

28.-29. (Canceled)

30. (Previously Presented) The method of claim 24, wherein the primary drying temperature is about 8° C.

31. (Canceled)

32. (Previously Presented) The method of claim 24, wherein the primary drying temperature in the primary drying stage is maintained for at least about 36 hours.

33. (Original) The method of claim 24, wherein the primary drying stage is carried out at a pressure of about 200 micron Hg or less.

34. (Original) The method of claim 33, wherein the primary drying stage is carried out at a pressure of about 80 micron Hg.

35. (Canceled)

36. (Previously Presented) The method of claim 24, wherein the first secondary drying temperature is about 35° C.

37. (Canceled)

38. (Previously Presented) The method of claim 24, wherein the second secondary drying temperature is about 45° C.

39. (Original) The method of claim 24, wherein the temperature of the frozen mixture in the secondary drying stage is changed at a rate of about 1° C per minute or less.

40. (Original) The method of claim 39, wherein the temperature of the frozen mixture in the secondary drying stage is changed at a rate from about 0.05 to about 0.1° C per minute.

41. (Canceled)

42. (Previously Presented) The method of claim 24, wherein the first secondary drying temperature in the secondary drying stage is maintained for at least about 15 hours.

43. (Canceled)

44. (Previously Presented) The method of claim 24, wherein the second secondary drying temperature in the secondary drying stage is maintained for at least about 18 hours.

45. (Original) The method of claim 24, wherein the secondary drying stage is carried out at a pressure of about 200 micron Hg or less.

46. (Original) The method of claim 45, wherein the secondary drying stage is carried out at a pressure of about 80 micron Hg.

47.-49. (Canceled)

50. (Original) The method of claim 24, wherein the composition is aseptically filtered and aseptically filled into a container after the completion of step (a) and before the completion of step (b).

51.-65. (Canceled)

62. (New) A method of producing a stable, sterile pharmaceutical formulation comprising lyophilized azithromycin, which method comprises:

(a) preparing a liquid composition comprising an ethanolate of Azithromycin, citric acid, and an aqueous solvent,

(b) chilling the composition to a temperature from about -10° C to about

15° C, wherein the temperature is maintained for at least about 20 minutes to about 2 hours,

(c) freezing the composition to a temperature of from about 10° C to about 70° C, to produce a frozen mixture, wherein the temperature is maintained for at least about 30 minutes to about 20 hours,

(d) subjecting the frozen mixture to a primary drying stage, which comprises applying a vacuum to reduce the pressure by an amount effective to remove aqueous solvent from the frozen mixture, and, while applying the vacuum, changing the temperature of the frozen mixture to a primary drying temperature, wherein the primary drying temperature is from about -30° C to about 20° C, and wherein the primary drying temperature is maintained for at least about 15 hours to about 50 hours, to produce a first intermediate, and

(e) subjecting the first intermediate to a secondary drying stage, which comprises applying a vacuum to reduce the pressure by an amount effective to remove aqueous solvent from the first intermediate, and, while applying the vacuum, (i) changing the temperature of the first intermediate to a first secondary drying temperature, wherein the first secondary drying temperature is from about 0° C to about 45° C, and wherein the first secondary drying temperature is maintained for at least about 5 hours to about 30 hours, and (ii) changing the temperature of the first intermediate to a second secondary drying temperature, wherein the second secondary drying temperature is from about 0° C to about 60° C, and wherein the second secondary drying temperature is maintained for at least about 5 hours to about 30 hours, to produce the pharmaceutical formulation, wherein ethanol is present in an amount from about 0.005% to about 0.5% by weight of the pharmaceutical formulation.